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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,084	12/06/2001	Kiichi Adachi	2130US	2648

22881 7590 12/17/2002

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EXAMINER

GUO, LYND A T

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 12/17/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/010,084

Applicant(s)

ADACHI ET AL.

Examiner

Lynda T Guo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Status of the Application***

The IDS PTO-1449 (Paper No. 6) received on 18 September 2002 has been entered.

Claims 1-49 of the present Application are pending and are subject to restriction election of species requirements.

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-7, drawn to methods of identifying a test compound, classified in class 435, subclass 7.31.
  - II. Claims 8-12 and 18, drawn to methods for identifying a test compound, classified in class 435, subclass 7.31.
  - III. Claims 13-17 and 19, drawn to methods of identifying a test compound, classified in class 435, subclass 7.31.
  - IV. Claims 20-25, drawn to a method for identifying a test compound, classified in class 435, subclass 29.
  - V. Claims 26-32, drawn to a method for identifying a test compound, classified in class 435, subclass 29.
  - VI. Claims 33-40, drawn to a method for identifying a test compound, classified in class 435, subclass 29.
  - VII. Claims 41-43, drawn to a method for identifying a test compound, classified in class 435, subclass 33.

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VIII. Claims 44, 45 and 47, drawn to an isolated nucleic acid, classified in class 536, subclass 23.2.

IX. Claim 46, drawn to an expression cassette, classified in class 435, subclass 320.1.

X. Claims 48-49, drawn to a polypeptide, classified in class 435, subclass 194.

The inventions are distinct, each from the other because of the following reasons:

2. The methods in Inventions I-VII are each different and patentably distinct inventions.

They are each patentably distinct because each requires materially different reagents, had different modes of operation, different functions and different effects.

3. The methods of Inventions I-VII are patentably distinct from the nucleic acid of Invention VIII and the expression cassette of Invention IX. Inventions VIII and IX are not disclosed as being usable in each of the methods of Inventions I-VII.

4. The methods of Inventions V-VII are patentably distinct from the polypeptide of Invention X. Invention X is distinct from Inventions V-VII because the polypeptide is not disclosed as being integral to the methods. (The methods, as claimed, measures the effect of a test compound on cell growth.)

5. The polypeptide of Invention X and the methods of Inventions I-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used in materially different processes, for example, the methods as disclosed in Inventions I-IV, each of which require different reagents.

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6. Inventions VIII, IX and X are each patentably distinct. They are distinct from each other because each invention is structurally, compositionally and/or chemically different. For example, Invention VIII is drawn to a nucleic acid sequence comprising Seq ID No. 1 and Invention IX is drawn to an expression cassette. Invention IX is compositionally different in that it will include promoter sequences among other sequences not included in Invention VIII. The polypeptide of Invention X is different from Inventions VIII and IX in that the former is composed of amino acids and the latter is composed of nucleic acids.
7. Because these inventions are distinct for the reasons given above and
- have acquired a separate status in the art as shown by their different classification;
  - have different and separately burdensome: manual and/or computer: structure, name and bibliographical searches; and
  - have divergent subject matter,
- restriction for examination purposes as indicated is proper.

#### *Election of Species*

8. This application contains claims directed to patentably distinct species of the claimed inventions:
- If applicant elects the method of Invention IV, applicant is required to elect a single species for the characteristic detected when measuring expression of histidinol-phosphatase (e.g. HISP1 mRNA of Claim 24 or histidinol-phosphatase polypeptide of Claim 25).
  - If applicant elects the method of Invention V, applicant is required to elect a single species for the histidinol-phosphatase (e.g. fungal – Claim 29, non-fungal – Claim 31 OR combination of both – Claim 32).
  - If applicant elects the method of Invention VI, applicant is required to elect a single species for the L-histidine biosynthesis genes (e.g. fungal – Claim 36, non-fungal – Claim 38 OR combination of both – Claim 39).

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9. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

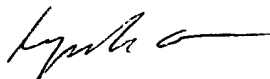
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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynda T Guo whose telephone number is (703) 605-1200. The examiner can normally be reached on Mon - Fri (8:00am - 4:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on (703) 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lynda T Guo  
Patent Examiner  
December 6, 2002



RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200